

10/526493

DT01 Rec'd PCT/PTC 04 MAR 2005

Application for

United States Letters Patent

of

Ibrahim H. IBRAHIM

for

**METHOD AND APPARATUS FOR MEASUREMENT OF
TRANSMITTER/RECEIVER SEPARATION**

Method and Apparatus for Measurement of Transmitter/Receiver Separation

Field of the Invention

5 The present invention relates to a method and apparatus for determining the position of an external transceiver relative to an implanted transceiver. The invention also relates to a method and apparatus for determining a skin flap thickness of a recipient of a prosthesis comprising a transcutaneous link provided by an external transceiver and an implanted transceiver, and to a skin-flap thickness meter.

10

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea
15 are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which comprise a microphone and an amplifier for amplifying detected sounds so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, the reason for deafness is
20 sensorineural hearing loss, which is caused by an absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.
25 It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4,532,930, the contents of which are incorporated herein by reference, provides
30 a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two essential components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a stimulator/receiver unit. Traditionally, both of these components have cooperated together to provide the sound
35 sensation to a user.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter coil.

5 The coded signal output by the speech processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the user. This transcutaneous transmission occurs via the external transmitter coil which is positioned to communicate with an implanted receiver coil provided with the stimulator/receiver unit. This communication serves two essential purposes, firstly to
10 transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link has been in the form of an RF link, but other such links have been proposed and implemented with varying degrees of success.

 The implanted stimulator/receiver unit traditionally includes a receiver coil that
15 receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

20 A particular problem that the present invention seeks to address is determining a distance of separation between an external transceiver and an implanted transceiver by determining the relative position of the external transceiver to the implanted transceiver. Aother problem is when an external transmitter or transceiver has been displace,. for example when the external transceiver has fallen away from an optimum
25 position upon the recipient. It is particularly relevant when the recipient, such as an infant, is unable to or unlikely to indicate such an occurrence and therefore cannot derive maximum hearing benefit from the implant system. Embodiments of the present invention may be particularly advantageous, as the distance between the transceivers impacts upon the amount of power that can be delivered to the implanted transceiver,
30 and hence impacts upon a power source current and useful life, for instance where the power source is a battery. As such embodiments of the present invention enable a determination of the distance to be made, transmission and stimulation parameters of transmissions between the transceivers may be optimised to allow for the actual distance of separation. Optimising such parameters for the actual distance of separation
35 leads to improved performance of the implant system, and also improves battery lifetime.

Embodiments of the present invention are particularly advantageous in that an actual field between the transmitter and receiver is measured. While an alternative prior art approach is to monitor a voltage standing wave ratio (VSWR) on the cable leading to the transmitter, such an approach requires an assumption that a change in the VSWR stems from an alteration in the link between the transmitter and receiver, whereas in fact such alterations in the VSWR may equally arise from a break in the cable or transmitter coil causing an open circuit or other such fault.

Furthermore, for the reasons given hereinbefore, the invention also seeks to provide an improved method of determining a skin-flap thickness of a recipient partly by determining the separation between the external transceiver and the implanted transceiver or stimulator/receiver. Prior art attempts at determining the separation have used battery current whereby the battery current is mapped to transceiver separation. However, measurement and monitoring of battery current may not change monotonically with varying transceiver separation, and therefore does not enable a one-to-one mapping of battery current to the separation. Conversely, measuring magnetic field strength, as with the present invention, provides a monotonic variation with transceiver separation and therefore provides a one-to-one mapping of magnetic field strength to transceiver separation.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention before the priority date of each claim of this application.

Summary of the Invention

According to a first aspect of the invention there is provided a method of determining a position of an external transceiver relative to an implanted transceiver, the method comprising the steps of:

measuring the strength of a magnetic field proximal to the external transceiver; and

determining a position of the external transceiver relative to the implanted transceiver from said measured magnetic field strength.

According to a second aspect of the invention there is provided apparatus for determining a position of an external transceiver relative to an implanted transceiver, the apparatus comprising:

means for measuring the strength of a magnetic field proximal to the external transceiver; and

means for determining a position of the external transceiver relative to the implanted transceiver from said measured magnetic field strength.

5 It has been realised that the magnetic field strength between two transceivers preferably forming a transcutaneous link is a particularly useful factor in determining the relative positioning of the transceivers. In particular, the magnetic field strength changes monotonically with varying transceiver separation, thus allowing a one-to-one mapping of magnetic field strength to transceiver separation. However, other factors,
10 such as battery current, may not change monotonically with varying transceiver separation, and thus do not enable a one-to-one mapping of battery current to transceiver separation, making it impossible to determine transceiver separation by monitoring or measuring such a factor.

Further, a measurement of magnetic field strength can be performed with very
15 little power consumption, and with very little loading effect on the transmissions between the external and implanted transceivers, thus providing the advantages of simple low current implementation.

The position of the external transceiver relative to the implanted transceiver may be determined simply in order to indicate whether the external transmitter has been
20 displaced, for example where the external transceiver has fallen away from a proper position upon the recipient. Such embodiments of the present invention are particularly useful where the recipient is unlikely to indicate such an occurrence, for instance where the recipient is an infant.

In such embodiments of the first aspect of the present invention, the step of
25 determining preferably further comprises a step of comparing a measured strength of magnetic field proximal to the external transceiver to a threshold value; and the method of the first aspect of the invention preferably further comprises the step of indicating that the external transceiver has been displaced when the measured strength of magnetic field proximal to the external transceiver exceeds the threshold value. The
30 step of indicating may comprise providing an audible indication such as an alarm, a visible indication or other indication.

Similarly, in such embodiments of the apparatus of the second aspect of the invention, the apparatus preferably further comprises means for comparing a measured strength of magnetic field proximal to the external transceiver to a threshold value; and
35 means for indicating that the external transceiver has been displaced when the measured strength of magnetic field proximal to the external transceiver exceeds the

threshold value. The means for indicating may comprise an audible alarm, a visible indicator, or other type of indicator.

Alternatively, the position of the external transceiver relative to the implanted transceiver may be determined in order to estimate a distance of separation between the external transceiver and the implanted transceiver. Such embodiments of the invention may be particularly advantageous, as the distance between the transceivers impacts upon the amount of power that can be delivered to the implanted transceiver, and hence impacts upon a power source current and useful life, for instance where the power source is a battery. As such embodiments of the present invention enable a determination of the distance to be made, transmission and stimulation parameters of transmissions between the transceivers may be optimised to allow for the actual distance of separation. Optimising such parameters for the actual distance of separation leads to improved performance of the implant system, and also improves battery lifetime.

In such embodiments of the first aspect of the invention, the step of determining preferably further comprises mapping a measured value of magnetic field strength proximal to the external transceiver to a distance value. The step of mapping may comprise consulting a look-up table comprising a plurality of pairs of values, each pair of values mapping a particular magnetic field strength to a corresponding transceiver separation distance.

Alternatively the step of mapping may comprise algorithmically converting said measured value of magnetic field into a corresponding transceiver separation distance..

Similarly, in such embodiments of the second aspect of the invention, the apparatus preferably further comprises means for mapping a measured value of magnetic field strength proximal to the external transceiver to a distance value. The means for mapping may comprise a look-up table comprising a plurality of pairs of values of magnetic field strength to transceiver separation distance.

Alternatively the means for mapping may comprise means for algorithmically converting said measured value of magnetic field into a corresponding transceiver separation distance.

According to a third aspect of the invention there is provided a method of determining a skin flap thickness of a recipient of a prosthesis comprising a transcutaneous link provided by an external transceiver and an implanted transceiver, the method comprising the steps of:

measuring a strength of a magnetic field proximal to the external transceiver when the external transceiver is positioned so as to implement the transcutaneous link; and

5 determining a skin flap thickness of the recipient by determining a position of the external transceiver relative to the implanted receiver from said measured magnetic field strength.

According to a fourth aspect of the invention there is provided apparatus for determining a skin flap thickness of a recipient of a prosthesis comprising a transcutaneous link provided by an external transceiver and an implanted transceiver,
10 the apparatus comprising:

means for measuring a strength of a magnetic field proximal to the external transceiver when the external transceiver is positioned so as to implement the transcutaneous link; and

15 means for determining a skin flap thickness of the recipient by determining a position of the external transceiver relative to the implanted receiver from said measured magnetic field strength.

A transcutaneous link formed by the external transceiver and the implanted transceiver may comprise an RF link. The transcutaneous link may be unidirectional, in that the external transceiver comprises a transmitter, and the implanted transceiver
20 comprises a receiver. Alternatively, it is envisaged that the transcutaneous link may be bidirectional, in that both the external transceiver and the implanted transceiver may transmit and receive signals across the transcutaneous link. In particular, it is envisioned that the external transceiver will be operable to transmit both data and power across the transcutaneous link, and to receive data across the transcutaneous
25 link. Similarly, it is envisioned that the implanted transceiver will be operable to receive both power and data across the transcutaneous link and to transmit data across the transcutaneous link.

The means for measuring the strength of the magnetic field proximal to the external transceiver may comprise a pickup coil positioned proximal to the external
30 transceiver. Preferably, the pickup coil is positioned in a plane substantially perpendicular to a primary axis of the magnetic field produced by the transceivers. The pickup coil may comprise an open circuited single turn, positioned concentrically with turns of the external transceiver. In such embodiments, a voltage induced on the pickup coil will be indicative of a magnetic field proximal to the external transceiver,
35 and may thus be used in determining a position of the external transceiver relative to the implanted transceiver.

The external transceiver will typically be capable of transmitting power and data to the implanted transceiver. However, the external transceiver is preferably capable of receiving data from the implanted transceiver. Similarly, the implanted transceiver will typically be capable of receiving power and data from the external transceiver, but is
 5 preferably also capable of transmitting data to the external transceiver.

It is to be appreciated that measurement of the magnetic field strength proximal to the implanted transceiver may similarly yield information regarding the position of the external transceiver relative to the implanted transceiver and is thus within the scope of the present invention. However it is unlikely that such internal field
 10 measurements will be efficient due to the limited power available to an implanted portion of a prosthesis, and the difficulty of processing and communicating such measurements from the implanted portion to the external transceiver.

According to a fifth aspect of the invention there is provided a skin-flap thickness meter, the meter comprising:

15 a meter transmitter coil for placement proximal to an implanted transceiver such that the meter transmitter coil and the implanted transceiver coil are separated by substantially the skin-flap thickness;

means for measuring a strength of a magnetic field proximal to the meter transmitter coil when the meter transmitter coil is placed proximal to the implanted
 20 transceiver; and

means for determining a skin flap thickness by determining a position of the meter transmitter coil relative to the implanted transceiver from said measured magnetic field strength.

According to a sixth aspect of the invention there is provided apparatus for
 25 determining a position of an external transceiver relative to an implanted transceiver, the apparatus comprising:

means for measuring the strength of a magnetic field proximal to the external transceiver;

means for determining a position of the external transceiver relative to the
 30 implanted transceiver from said measured magnetic field strength;

means for comparing a measured strength of magnetic field proximal to the external transceiver to a threshold value;

means for indicating that the external transceiver has been displaced when the measured strength of magnetic field proximal to the external transceiver exceeds the threshold value; and

means for mapping comprises a look-up table comprising a plurality of pairs of values of magnetic field strength to transceiver separation distance.

According to a seventh aspect of the invention there is provided apparatus for determining a skin flap thickness of a recipient of a prosthesis comprising a transcutaneous link provided by an external transceiver and an implanted transceiver, the apparatus comprising:

- 5 a pick-up coil for measuring a strength of a magnetic field proximal to the external transceiver when the external transceiver is positioned so as to implement the transcutaneous link, the pickup coil being positioned in a plane substantially perpendicular to a primary axis of the magnetic field produced by the transceivers;

- 10 wherein a voltage induced on the pickup coil is indicative of a magnetic field proximal to the external transceiver; and

means for determining a skin flap thickness of the recipient by determining a position of the external transceiver relative to the implanted receiver from said measured magnetic field strength.

15 **Brief Description of the Drawings**

Preferred embodiments of the invention will hereinafter be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a pictorial representation of a cochlear implant system within which the present invention may be implemented;

- 20 Figure 2 is a circuit diagram illustrating implementation of an embodiment of the present invention;

Figure 3 depicts variation of magnetic field strength with transceiver separation for the embodiment of Figure 2;

- 25 Figure 4 depicts variation of battery current with transceiver separation for the embodiment of Figure 2;

Figure 5 is a circuit diagram illustrating a coil-off detection circuit in accordance with the present invention;

Figure 6 is a circuit diagram of a circuit used for verification of coil-off detection;

- 30 Figure 7 illustrates the variation of magnetic field with transceiver separation for particular values of stimulation rate and sound level for the circuit of Figure 6;

Figure 8 illustrates the variation of magnetic field with transceiver separation for particular values of supply voltage and sound level for the circuit of Figure 6;

Figure 9 illustrates the variation of magnetic field with transceiver separation for particular values of implanted coil tuning and sound level for the circuit of Figure 6; and

Figure 10 illustrates the variation of magnetic field with transceiver separation
5 for particular values of external coil tuning and sound level for the circuit of Figure 6.

Detailed Description of the Preferred Embodiments

While the present invention is not directed solely to a cochlear implant, it is appropriate to briefly describe the construction of one type of known cochlear implant
10 system with reference to Figure 1.

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and
15 arranged so that it can fit behind the outer ear 11. Alternative versions may be worn elsewhere on the recipient's body. Attached to the speech processor 29 is a transmitter coil 24 that transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The implanted component includes a receiver coil 23 for receiving power and
20 data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4,532,930. As
25 depicted diagrammatically in Figure 1, the cochlear implant electrode array 20 has traditionally been inserted into the initial portion of the scala tympani of the cochlea 12 up to about a full turn within the cochlea.

A sound processor (not shown) of the external component 29 includes an amplifier and a speech processor that uses a coding strategy to extract speech from the
30 sounds detected by the microphone 27. In the depicted embodiment, the speech processor of the cochlear implant can perform an audio spectral analysis of the acoustic signals and output channel amplitude levels. The sound processor can also sort the outputs in order of magnitude, or flag the spectral maxima as used in the SPEAK strategy developed by Cochlear Ltd. Other coding strategies could be employed.

35 Figure 2 is a circuit diagram illustrating implementation of an embodiment of the present invention in a cochlear implant system of the type shown in Figure 1. The

speech processor of the external component 29 drives the transmitter coil 24, which transmits power and data to receiver coil 23, for the implanted stimulator unit 22. In accordance with the present invention, a pickup coil 30 is provided for detecting the strength of a magnetic field proximal to the transmitter 24. The pickup coil 30 is
5 positioned in a plane substantially perpendicular to a primary axis of the magnetic field produced by the transmitter coil 24 and receiver coil 23. The pickup coil comprises an open circuited single turn, positioned concentrically with turns of the transmitter coil 24. A voltage is induced on the pickup coil which is indicative of a magnetic field strength proximal to the transmitter coil 24. The output of the pickup coil 30 is passed
10 through a peak detector comprising diode D and capacitor C.

In the present embodiment, the RF link of the implant system operates at a signal frequency of 5MHz. The transmitter coil 24 and receiver coil 23 are stagger-tuned to achieve the bandwidth needed for a 100% amplitude modulated RF signal. The transmitter resonance circuit 24 is usually tuned below the signal frequency, while
15 the implant receiver circuit 23 is tuned slightly above the signal frequency. As a result, the effective impedance seen by the RF drivers of the speech processor of the external component 29, at the signal frequency, is inductive. This inductive impedance increases when the coupling between the coils 23, 24 is increased, by reducing the distance between the coils 23, 24. As a result, the current through the transmitter coil
20 24, and the magnetic field in the vicinity of the coil 24, falls when the distance between the coils is reduced.

This phenomena can also be explained in terms of the interaction between the magnetic fields surrounding the transmitter coil 24 and receiver coil 23. The magnetic field generated by the receiver coil 23 is a secondary field that opposes the primary
25 field of the transmitter coil 24. The interaction between the two opposite fields reduces the effective field near the transmitter coil 24. This effect is increased as the distance between the coils 23, 24 is reduced.

The invention is based on measuring the strength of the magnetic field in the vicinity of the transmitter coil 24. As this field increases monotonically with the
30 distance between the transmitter coil 24 and receiver coil 23, the measured field strength can be calibrated to estimate the distance between the coils 23, 24, and also to indicate if that distance exceeds a preset value, for example if the coil has fallen off the user's head.

However, other factors, such as battery current, may not change monotonically
35 with varying transceiver separation, and thus do not enable a one-to-one mapping of

battery current to transceiver separation, making it impossible to determine transceiver separation by monitoring or measuring such a factor.

Further, a measurement of magnetic field strength can be performed with very little power consumption, and with very little loading effect on the transmissions
 5 between the external and implanted transceivers, thus providing the advantages of simple low current implementation.

The circuit shown in Figure 2 was simulated using OrCad Pspice version 9.2. The simulation model included circuit models for the CI24M implant produced by Cochlear Ltd, ESPrit 3G speech processor produced by Cochlear Ltd and a single turn
 10 pickup coil.

A simplified spice model was used for both the implant and the speech processor. The ESPrit 3G model included the major variable that affects and/or sets the battery current, output RF current, stimulation phase width, and intra-frame gap, as well as the RF-data mark-space ratio. The implant model, on the other hand, included
 15 all the power consuming components such as the antenna resistance, transformer losses, diode, IC consumption and stimulation current. The coupling coefficient, k , between the transmitter and receiver coils was expressed as a function of the distance d between the coils:

$$k = \frac{1.26}{2.6 + d}, \text{ where } d \text{ is in mm.}$$

20

This value of k was empirically obtained from the particular antennae used in the circuit depicted in Figure 2. The peak detector decay time constant was set to 10ms. This time constant was chosen much longer than the stimulation period of the
 25 SPEAK strategy, set to 2000pps in the Spice model.

The circuit was simulated using stimulation rates from 2000pps to 13900pps, stimulation current ranging from 0 to 1.8mA and link range from 1 to 20mm. The circuit parameters shown in the following table were used to study the effect of the distance between the coils.

30

35

Parameter	Value
Vbatt	3.0V
Stim rate	13.9kHz
Phase width	25us
Stim current	1mA

Parameter	Value
Transmitter coil tuned freq	4.8MHz
Receiver coil tuned freq	5.25MHz
Pickup inductance	60nH
Coupling coefficient of pickup coil	0.7

The simulation results are shown in Figure 3 and Figure 4. Figure 3 depicts the peak detector output voltage versus link range (transmitter 24 / receiver 23 separation). This output voltage depends on the strength of the magnetic field, normal to the pickup coil 30. In this example, the pickup coil 30 is a single track printed on a PCB upon which the transmitter coil 24 is also printed. The coupling coefficient between the transmitter 24 and pickup coil 30 is assumed to be 0.7. Higher coupling can be achieved in practice by the careful placement of the pickup coil 30 relative to the transmitter 24. Higher output signals can also be obtained if a two-turn (or more) pickup coil is used.

Figure 3 reveals that the magnetic field of the transmitter 24 increases with the distance between the transmitter coil 24 and receiver coil 23 (link range). When that distance exceeds 20mm, the output voltage reaches about 780mV (not shown in the figure). Figure 3 also reveals that the increase in magnetic field is monotonic as the link range increases from 1mm to 10mm.

Figure 4 depicts the battery current, which reaches a peak value of 18.9mA at 4mm then gradually drops to 18mA at 10mm, and to 17mA at 20mm (not shown in the figure). Thus, the battery current does not vary monotonically with increasing link range between the transmitter 24 and receiver 23.

Figures 3 and 4 clearly show that the battery current cannot be used to estimate the link range, as a given value of battery current can not be equated to a single value of transceiver separation. On the other hand, there is a one to one correlation between the output voltage of the peak detector C, D and the distance between the transmitter coil 24 and receiver coil 23.

It is to be noted that the battery current is proportional to the total system power. On the other hand, the strength of the magnetic field in the vicinity of the transmitter coil 24 is proportional to the stored reactive energy. The relationship between the active and reactive energy components depends on the phase angle of the coil current relative to the driving voltage. It is this phase angle which changes with the coupling coefficient between the transmitter coil 24 and receiver coil 23.

The peak detector output depends slightly on the implant power, as explained below with respect to Figures 5 to 10. The effect of the implant power on the output of the peak detector becomes negligible at maximum link range.

As the distance between the coils 23, 24 is gradually increased from minimum to maximum link range, a number of effects occur. Firstly, the power delivered to the implant 22 is reduced. Secondly, transmitter losses increase due to increased RF current.

These changes determine the behaviour of the battery current, whereas the current through the transmitter coils 23, 24, and hence the magnetic field strength, increases monotonically towards an asymptotic value.

The peak magnetic field, normal to the pickup coil 30, depends on the sum of the electric fields produced by the transmitter coil 24 and receiver coil 23. The peak magnetic field depends slightly on the stimulation parameters, namely the stimulation current and the stimulation rate. The influence of the stimulation parameters is relatively small because the stimulation power represents a small part of the total system power which includes the implant 22 and transmitter coil 24 losses, as follows:

Total transmitter coil power = transmitter coil losses + implant losses + stimulation power

On the other hand, the ratio of the stored to dissipated energy is the effective quality factor of the loaded transmitter coil, as follows:

$Q = \text{stored energy per cycle} / \text{dissipated energy per cycle} = \text{reactive power} / \text{dissipated power}$

But $Q \gg 1$, therefore Reactive power \gg dissipated power, which yields:

Reactive power \gg transmitter coil losses + implant losses + stimulation power

That is, Reactive power \gg Stimulation power.

The magnetic field is proportional to the reactive power, which is much higher than the stimulation power. Therefore, the stimulation parameters can only have a second order effect on the peak amplitude of the magnetic field. This is in agreement with the simulation results.

The stimulation rate, however, has a stronger effect due to the fact that the peak detector used in Figure 2 is not ideal and has a finite decay time constant.

The significance of the above discussion is to highlight the fact that, at long link range, the peak detector output is not sensitive to the stimulation current, but is affected

by the stimulation rate. This effect must be taken into account when the peak detector output is used to estimate the distance between the coils.

One application of the present invention is in estimating a skin flap thickness of a recipient of a cochlear implant system of the type shown in Figure 1, that is, the thickness of skin between the implanted receiver coil 23 and the external transmitter coil 24.

To date, estimating the skin flap thickness has been done in a clinic where the speech processor is powered from the programming system. In this case, specific stimulation parameters are used in order to achieve consistent and repeatable skin flap thickness estimates.

However, the circuit of Figure 2 can be used to estimate the skin flap thickness. A first method by which the skin flap thickness may be estimated by using the circuit of Figure 2, involves using the recipient's own speech processor to create the RF magnetic field. This method requires providing a signal path from the peak detector output to the programming system. In this case, the transmitter coil is excited with maximum frame rate at a regulated supply voltage supplied by the programming system. This eliminates the dependency of the peak detector output on the stimulation rate and supply voltage. A look up table stored in the programming system can be used to map the measured voltage to skin flap thickness.

A second method by which the skin flap thickness may be estimated by using the circuit of Figure 2, involves using a stand-alone device with built-in oscillator and voltage measurement circuit. In this second method, the stand-alone device is essentially a skin flap thickness meter. The meter contains a 5MHz crystal oscillator with low output impedance drivers to drive a tuned transmitter coil with continuous 5MHz square voltage. The transmitter coil contains a pickup coil and a peak detector similar to that shown in Figure 2. The DC output of the peak detector is measured using a built-in analog to digital converter (ADC). The output of the ADC is converted to skin flap thickness, which is then displayed by the meter.

Another application of the present invention is in detecting displacement of the external transmitter 24 from the user's head, for example where the transmitter coil 24 falls off an infant's head. Such coil-off detection is based on detecting a link range greater than a set threshold value, which would typically be set to around 10-12mm. Such a circuit solution has to be implemented on the transmitter coil and/or the speech processor. For reliable detection, the circuit has a low sensitivity to battery voltage, stimulation current, stimulation rate, ambient temperature and implant tuning. The circuit also operates without requiring precision measurement of the output voltage of

the peak detector. The circuit solution is simple, uses a small number of components and has low current consumption.

One manner in which many or all of the above requirements may be met is by comparing the peak detector signal with another reference signal, which has all of the major characteristics of the peak detector signal except its dependency on the coil separation. The reference signal should be generated from a peak detector similar to that shown in Figure 2 in order to have the same decay time constant, voltage offsets and temperature characteristics as the measured signal, and should be proportional to the battery voltage to track the changes of the measured signal with the battery voltage. Further, the reference signal should vary with the stimulation rate in a manner similar to that of the measured signal, and should have low sensitivity to the implant power, especially at relatively large link ranges.

A simple manner in which the reference signal can be obtained comprises rectifying and peak-detecting the output of the RF drivers of the speech processor, as shown in Figure 5. In Figure 5, the output of the speech processor, in this instance an ESPrit 3G speech processor of the type produced by Cochlear Ltd, is full-wave rectified by D_1 and D_2 . The DC voltage across C_2 tracks the amplitude of the ESPrit 3G RF output voltage. This DC voltage can be made to vary with the stimulation rate in a manner which is similar to that of the voltage across R_1 . This is determined by the time constant:

$$\tau_1 = C_2 \cdot (R_2 + R_3)$$

When this time constant is made very small, the voltage across C_2 will strongly depend on the stimulation rate, and vice versa.

The voltage divider ratio $R_3 / (R_2 + R_3)$ is designed such that the voltage across R_3 is substantially equal to the peak voltage across R_1 at the designated threshold for the maximum link range. The voltage across R_3 is applied to a diode-capacitor (D_4 , C_3) peak detector similar to that used with the pickup coil 30. This is to match the time variation and the temperature characteristics of the measured signal and the reference signal.

A voltage comparator is used to compare the measured and reference signals. The output of the comparator can be used to trigger an audible alarm to alert the carers if the transmitter coil is removed.

The way the circuit operates is based on matching the amplitudes of the measured and reference signals at the maximum link range. Below that range, the

measured signal is smaller and the output of the comparator is disasserted. However, if the separation between the transmitter coil 24 and receiver coil 23 exceeds the maximum link range, the measured signal exceeds the reference signal and triggers the comparator.

5 The recommended component values for typical circuit conditions of the ESPrit 3G are given below.

D1 to D4: low cut-in voltage high-speed diodes

R1 = R4 = $1\text{M}\Omega$

R2 = $220\text{k}\Omega$

10 R3 $\cong 100\text{k}\Omega$

C1 = C3 = 10nF

C2 = 100pF

Pickup coil: printed single turn on the transmitter coil PCB. A single turn from an electrostatic shield can be used.

15 Where the transmitter coil is implemented on a printed circuit board, the circuit of Figure 5 can be fully integrated on the PCB of the transmitter coil. The comparator can be replaced with a low voltage-low power low speed operational amplifier. The DC power for the comparator/amplifier can be provided from the RF drivers' signal using a voltage doubler circuit to provide the amplifier with positive and negative DC
20 supply rails. A power cost will be in overloading the RF drivers with the comparator DC power, which can be as low as $50\mu\text{A}$ at 3V . However, this is an insignificant cost compared with the total RF power consumed by the system. The advantage of integrating the circuit on the transmitter coil is that it reduces the number of the coil cable connectors, and substantially guarantees the matching between the circuit
25 components especially with respect to changes with temperature.

Figure 6 is a circuit diagram of a circuit used for verification of coil-off detection, for use with an ESPrit 3G speech processor. The circuit of Figure 6 was used to investigate and verify the concept and to study the sensitivity to different circuit and stimulation parameters. The prototype was measured in a laboratory with both
30 SPEAK and 14.2 kHz stimulation, at both quiet and loud sound environments, and at different battery voltages.

The circuit is designed for minimum loading on the RF drivers of the ESPrit 3G. It uses a small number of components which can be all mounted on the transmitter coil printed circuit board. The transmitter coil has 3 open tracks on each side used for
35 electrostatic shielding. One shield track (nearly a full turn) is used as the pickup coil.

R_1 , R_2 and C_2 form a potential divider and a low pass filter for the RF signal on RFOUT 1. The filter parameters are chosen such that the peak voltage across C_2 varies with the pulse width of the RF signal. This allows the output V1 to track the RF power level at different battery voltages. In Figure 6 R_1 is a variable resistor to facilitate
 5 accurate adjustment for the best detection thresholds. In a non-testing circuit, it is expected that R_1 will be replaced with a fixed resistor.

The voltage across C_{10} and the voltage across the pickup coil L_2 are peak detected using identical envelope detectors. The DC output V1 is the coil-off detection voltage threshold. V2 is the coil-off signal. The voltage V2 increases as the separation
 10 between the transmitter coil and the implanted receiver coil increases. At or above the coil-off detection distance, V2 exceeds V1.

The measurement method was as follows. The ESPrit 3G was loaded with 2 patient maps. The first was a 14.2 kpps map while the second was a SPEAK 2 kpps map. A “quiet” sound condition was simulated by removing the microphone and
 15 replacing it with a $1k\Omega$ resistor. A “loud” sound condition was simulated by placing a loud radio close to the microphone. The voltages V1 and V2 were measured under the conditions shown in table 1 below.

Each of the following tests was carried out at room temperature. A total of 40 tests (table 1) were carried out. During each test the distance was varied from 0 to
 20 14mm in 2mm steps, after which the distance was set to more than 10cm (simulating very large distance). These 40 tests cover the different circuit parameters, in order to demonstrate the sensitivity of the coil-detection method to these parameters.

At each distance, the test was repeated 4 times; at stimulation rates of 2000pps and 14400pps, and in both “quiet” and “loud” sound environments. The measurements
 25 were also repeated at different implant tuning frequencies of 5.1MHz, 5.25MHz and 5.4MHz, and at different supply voltages of 2.7V, 3.0V and 3.3V.

To check the sensitivity to the transmitter coil tuning the test was repeated for implant tuning of 5.25MHz and power supply voltage of 3V. The transmitter coil was tuned to its minimum limit and then to its maximum limit of 4.725MHz and 4.775MHz
 30 respectively.

Table 1: Test Conditions

Test Number	Transmitter Coil Tuning Frequency	Implant Coil Tuning Frequency	VDD	Stimulation Rate	Sound level
1	4.775 MHz	5.1MHz	2.7V	2000pps	Quiet
2					Loud
3				14200pps	Quiet
4					Loud
5			3.0V	2000pps	Quiet
6					Loud
7				14200pps	Quiet
8					Loud
9			3.3V	2000pps	Quiet
10					Loud
11				14200pps	Quiet
12					Loud
13		5.25MHz	2.7V	2000pps	Quiet
14					Loud
15				14200pps	Quiet
16					Loud
17			3.0V	2000pps	Quiet
18					Loud
19				14200pps	Quiet
20					Loud
21			3.3V	2000pps	Quiet
22					Loud
23				14200pps	Quiet
24					Loud
25		5.4MHz	2.7V	2000pps	Quiet
26					Loud
27				14200pps	Quiet
28					Loud

29			3.0V	2000pps	Quiet
30					Loud
31				14200pps	Quiet
32					Loud
33			3.3V	2000pps	Quiet
34					Loud
35				14200pps	Quiet
36					Loud
37	4.725 MHz	5.25MHz	3.0V	2000pps	Quiet
38					Loud
39				14200pps	Quiet
40					Loud

The test results are set out towards the end of the present specification. The distances at which the measured signal (V2) exceeds the threshold voltage (V1) are highlighted in the results tables. Because the measurements were done at increments of 2mm, the highlighted points could be equal to or exceed the correct detection point by up to 2mm.

Figure 7 illustrates the reference and measured voltages, V1 and V2 respectively, at 14.2kpps and 2kpps in quiet and loud sound environments. The battery voltage was set to 3.3V. The implanted coil was tuned to its nominal frequency of 5.25MHz. Figure 7 shows that the reference voltage is automatically adjusted to a threshold distance of between 12 and 13mm. Above this threshold, an alarm will be triggered to indicate a coil-off condition.

Figure 8 depicts the reference and measured voltages, V1 and V2 respectively, at 14.2kpps in quiet and loud sound environments, and at supply voltages of 3.3, 3.0 and 2.7V respectively. The implanted coil was tuned to its nominal frequency of 5.25MHz. These results indicate the detection distance has low sensitivity to the supply voltage, as the point of intersection of the V1 and V2 curves varies by only small amounts.

Figure 9 reveals that the coil-off detection distance is reasonably sensitive to the tuning frequency of the implanted coil. When the implant is tuned to 5.4MHz, the detection threshold distance drops to 8.5mm. The detection distance increases as the tuning frequency of the implanted coil is reduced to 5.1MHz. At this frequency, the circuit will detect coil removal if the distance exceeds about 14mm.

The effect of the transmitter coil tuning is shown in Figure 10. The results, at 3V supply voltage and 14.2 kHz stimulation rate, indicate that varying the transmitter coil tuning from 4.725MHz to 4.775MHz has substantially no effect on the distance threshold.

5

Summary of results

High rate stimulation

Test #	Detection Distance	Test #	Detection Distance	Test #	Detection Distance
3	10.8	15	9.5	27	6.3
4	11.4	16	9.5	28	6.2
7	11.8	19	9.6	31	6.2
8	11.8	20	9.6	32	6.2
11	14.9	23	11.9	35	8.5
12	15	24	12.3	36	8.5

10 The above table shows the coil-off detection threshold distance at all combinations of supply voltage and tuning frequencies.

Low rate stimulation

15 Similar to the high rate stimulation, the lowest detection distance occurred at low battery voltage and high implant tuning frequency (tests 25,26,29 and 30).

Test #	Detection Distance	Test #	Detection Distance	Test #	Detection Distance
1	6.5	13	6.7	25	5.3
2	8.4	14	7.9	26	5.6
5	7.0	17	6.9	29	5.5
6	9.3	18	8.8	30	6.0
9	13.7	21	12	33	9.1
10	13.9	22	12.7	34	9.2

The measurement results discussed above show the usefulness of the coil-off detection circuit embodiment of the present invention. The method discussed has low sensitivity to most of the circuit parameters and variables, except for the implant tuning if at the upper end of the tuning range. This problem can be easily solved by adding a
5 small DC offset to the reference voltage V_1 . By adjusting the value of that offset a detection distance in the range 8mm to 15mm can be achieved for all circuit conditions.

While an embodiment of the invention has been discussed in which a threshold detection of a coil-off condition is performed, it is to be appreciated that alternative embodiments of the present invention may be used to estimate an actual distance
10 between implanted and external coils. For example, a look-up table may be experimentally derived from a voltage to distance calibration measurement, such as the voltage measurements revealed in Figures 7 to 10. Such a look-up table may then be used in converting measured magnetic field strengths to estimated transceiver separation values. Alternatively, a best-fit algorithm may be derived from the
15 measured voltage/distance values, for use in converting measured magnetic field strengths to estimated transceiver separation values.

Appendix
Test Results

Distance	Test 1		Test 2		Test 3		Test 4	
Mm	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	254	29	306	46	412	93	463	136
2	258	42	323	65	435	108	502	157
4	248	90	341	107	453	146	532	194
6	227	196	343	177	473	205	575	267
8	228	311	283	270	423	292	519	330
10	230	387	302	359	414	388	494	436
12	227	422	288	415	425	463	482	506
14	225	446	286	462	446	537	478	566
>100	222	565	270	609	440	789	457	811

5

Distance	Test 5		Test 6		Test 7		Test 8	
Mm	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	323	56	405	93	634	262	635	263
2	329	72	405	105	664	274	664	275
4	318	129	419	155	706	316	707	318
6	298	234	415	236	746	391	746	391
8	297	367	400	339	732	477	733	479
10	300	470	408	442	673	586	673	586
12	298	509	409	512	662	671	662	671
14	296	536	412	566	654	741	654	740
>100	292	654	338	746	627	1005	632	1010

Distance	Test 9		Test 10		Test 11		Test 12	
Mm	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	544	137	633	190	773	340	773	340
2	530	131	638	192	796	335	797	336
4	553	169	654	223	835	356	833	357
6	569	249	685	294	874	421	874	422
8	585	359	645	382	865	499	865	499
10	599	473	630	487	811	607	811	607
12	605	555	631	569	802	697	802	697
14	612	621	631	635	797	773	797	772
>100	612	850	623	862	774	1034	774	1033

Distance	Test 13		Test 14		Test 15		Test 16	
Mm	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	254	35	349	74	414	105	473	152
2	259	57	290	70	430	138	485	180
4	266	112	306	124	436	194	475	227
6	224	197	263	200	424	269	476	312
8	226	280	278	283	417	358	472	409
10	232	340	272	345	410	431	464	486
12	225	338	264	389	443	524	463	537
14	223	418	276	448	439	581	462	608
>100	220	565	267	612	436	786	456	813

Distance	Test 17		Test 18		Test 19		Test 20	
Mm	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	328	67	415	114	641	276	637	274
2	334	100	428	145	666	326	661	316
4	334	176	438	208	679	409	674	385
6	297	257	459	310	681	487	676	478
8	298	351	490	372	663	579	660	574
10	304	422	420	462	646	664	645	662
12	299	467	405	518	640	730	647	737
14	296	506	427	592	632	793	640	801
>100	292	659	432	793	624	1009	635	1022

Distance	Test 21		Test 22		Test 23		Test 24	
Mm	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	585	177	646	216	775	348	774	345
2	593	206	660	248	797	373	797	377
4	605	264	653	297	812	437	810	436
6	601	346	662	383	815	522	815	524
8	588	485	647	462	798	616	805	610
10	593	529	642	558	785	712	790	711
12	594	593	640	618	778	780	786	774
14	594	648	636	677	773	838	780	838
>100	594	856	631	874	762	1040	771	1038

Distance Mm	Test 25		Test 26		Test 27		Test 28	
	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	256	50	293	68	417	134	463	173
2	256	93	317	129	416	200	458	242
4	257	170	285	192	408	296	456	350
6	224	259	260	280	410	396	447	439
8	229	327	265	351	412	488	452	531
10	229	383	263	406	438	578	461	610
12	224	426	263	457	439	629	452	646
14	225	466	258	492	439	671	455	692
>100	222	582	255	615	440	809	458	833

Distance Mm	Test 29		Test 30		Test 31		Test 32	
	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	325	88	388	124	637	315	637	316
2	326	141	388	185	647	409	648	409
4	329	226	406	290	641	517	641	517
6	293	327	380	379	636	624	636	625
8	298	407	382	470	631	721	631	721
10	299	461	395	534	629	785	629	786
12	295	509	388	581	627	842	627	842
14	294	553	392	634	628	893	628	893
>100	292	678	378	758	627	1038	627	1039

Distance Mm	Test 33		Test 34		Test 35		Test 36	
	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	578	204	636	245	777	383	777	386
2	548	248	644	326	790	474	791	474
4	570	366	620	406	786	580	786	579
6	572	462	622	499	783	675	783	675
8	594	556	628	585	781	760	781	760
10	606	636	625	654	778	836	778	836
12	608	690	624	705	777	889	777	888
14	607	734	628	754	776	933	776	933
>100	610	878	623	891	774	1070	774	1070

Distance Mm	Test 37		Test 38		Test 39		Test 40	
	2.0kHz Quiet		2.0kHz Loud		14.2kHz Quiet		14.2kHz Loud	
	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)	V1 (mV)	V2 (mV)
0	325	71	405	115	636	286	637	287
2	330	98	417	146	659	326	659	327
4	341	166	428	208	671	398	671	398
6	296	259	423	295	673	488	673	489
8	294	342	405	378	658	578	658	578
10	301	403	407	447	639	659	640	660
12	297	442	412	500	632	716	632	716
14	293	475	408	549	626	768	627	768
>100	290	600	403	695	619	943	619	943

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as
5 illustrative and not restrictive.